

QUESTIONNAIRE – DEVELOPMENT OF A POLYCLONAL ANTIBODY BASED IMMUNOGENICITY ASSAY FOR A PROTEIN

Please fill out this form as a prerequisite for planning and specifying the major steps of the respective project.

It will also be used as the basis for quotation and further discussion of project details.

All information provided including the client information at the end of this questionnaire will be treated strictly confidential. A nondisclosure agreement can be signed upon request.

1. ANTIGEN INFORMATION – PROTEIN

Protein name: _____

Protein family: _____

Protein function: _____

Origin of protein: Human

Other, please specify: _____

Please specify species information: _____

Is any biosafety level required for handling?

Yes

No

Expression system:

Please specify the expression system: _____

If recombinantly expressed, is the protein a fusion protein?

Yes

No

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If yes, which tag has been used as fusion partner:

His-Tag, please add sequence of the tag:

GST-Tag, please add sequence of the tag:

Other, please specify tag sequence and
provide molecular weight (in kDa):

**Please provide molecular weight of the
antigen protein (in kDa):**

Purity:

Is the protein available in buffer?

Yes

No

If yes, please answer the following questions:

Soluble

Precipitated

Does the buffer contain a preservative? (BioGenes does not recommend the use of
preservatives)

No

Yes. Please specify preservative:

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2. ANTIBODY DEVELOPMENT

Immunization protocol for:

- Rabbit (recommended) Goat

Immunization with:

- Whole molecule F(ab')₂-Fragment
 Fab-Fragment scFv/Fv-Fragment

3. PREPARATION OF POLYCLONAL ANTI-IDIOTYPIC ANTIBODIES

Should preservatives be added prior to polyclonal anti-idiotypic antibody shipment?

- Yes, please add the following: No
 NaN₃ ProClin 0.2 µm filtrated Not filtrated
 Other, please specify: _____

Should cross-reactivity testing be included?

- Yes No I am not sure yet

If yes, please indicate kind of selection:

- Positive Negative Cross-reactivity test for characterization only

Are cross-reactants (commercially) available?

- Yes No

Name: _____

Purity [%]: _____

Molecular weight [kDa]: _____

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Cross-reactants are available in buffer Soluble Precipitated

Is further information about cross-reactants available (please provide)?

Are there antibodies against the selected antigen commercially available?

4. INFORMATION ABOUT THE INTENDED IMMUNOGENICITY ASSAY

Please estimate the required detection range of the ELISA

Please estimate the expected shelf life of the assay and the number of tests (per year)

Did you already contact a CRO? If yes, please provide details

An early contact with CRO is necessary in order to discuss specific requirements and plans regarding the assay.

If no CRO has been selected yet, BioGenes recommends its preferred partner for these services FyonBio, Berlin/Germany, www.fyonibio.com.

Are serum samples already available (i.e., from early stages of clinical trials)?

Serum samples are necessary for the characterisation and selection of the antibody pairs during assay development.

If no serum samples are available, please provide information about patient specification (i.e., gender, age, disease, additional medication). BioGenes will purchase sera with the respective specifications and spike them with the drug.

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5. PLEASE PROVIDE ADDITIONAL INFORMATION ON:

Planned timelines

Purchasing planned directly or via a
purchasing platform (e.g. Scientist.com)

How did you find out about BioGenes?

Other information not previously
covered?

CLIENT INFORMATION

Company/Institution name:

Contact person:

Address:

Phone:

Email:

Date: